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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,743	05/09/2001	James Nolan	00-388-A	4067

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EXAMINER
SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
1617	9

DATE MAILED: 06/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/851,743	NOLAN ET AL.N	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communicati n appears on the c ver she t with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-16,18-26,28-31,33 and 34* is/are pending in the application.

4a) Of the above claim(s) *8-12 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-7, 13-16, 18-19, 25-31, 33-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Amendment filed on April 03, 2003 has been entered. Claims 1-4, 6-16, 18-31, 33-34 are pending. Claims 8-12, 20-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-4, 6-7, 13-16, 18-19, 25-31, 33-34 are under consideration.

Any rejection that is not addressed in this Office Action is considered obviated

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The effective priority date of this application is May 9, 2000.

Claim Rejections - 35 USC § 112

Claims 1-4, 6-7, 13-16, 18-19, 25-31, 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "more rapidly," "more completely," or "less painfully" in claims 1 and 13 is a relative term which renders the claim indefinite. These terms are not defined by the claim and are in general subjectively measured among individuals.

Applicant's argument with respect to said limitations have been fully considered but are not found persuasive. Applicant argues that said recitation read in view of the specification is definite, because the comparison is in the presence of a control wound

treated in the absence of the test compound. Applicant then cites page 14, lines 24-26 to justify his argument.

In response, Examiner states that the cited page describes a comparative examination between the test compound and a "normal" control who is treated with a positive control for wound healing. However, the scope of the pending claims and the cited pages are not the same. The scope of the instant claims is directed to such methods that do not require such comparison with a normal control. Moreover, the specification does not define the relative nature of the limitations in question in view of a normal control. Accordingly, said limitations are viewed given their broadest reasonable interpretation and their metes and bounds as a whole is ambiguous.

Applicant is reminded, "an essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." See MPEP 2106. While it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not impose that limitation. It is well settled in Patent Law that reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from `reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." *In re Morris,* 127, F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-1028 (Fed. Cir. 1997). Accordingly, Applicant's reasoning is flawed and the arguments are not found persuasive.

Claim R j cti ns - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-7, 13-16, 18-19, 25-26, 28-31, 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al US Patent 5,232,341 in view of Jones et al Wo 99/50268 ('268) and Spence US Patent 4,226,232.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that the primary reference do not teach methods of identifying compounds that improve wound healing in diabetic animal. (see Remarks at page 8).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case the rejection is based on the combined teachings of the references. Since all limitations of the instant claims are taught in the cited references, the claims are *prima facia* for the reasons of record.

Further, Applicant arguments that the teachings of Jones which provides for the use of Aldose Reductase Inhibitors ("ARIs") as a model for diabetic animals, is only directed to claims 2 and 14 is noted. (see Remarks at page 9). However, claims 2 and 14 are dependent on claims 1 and 13. If claims 2 and 14 are rejected over cited prior art, surely scope of claims 1 and 13 are also *prima facia* obvious over the same art. In

brief, the argument that dependent claim can be rejected but not their respective independent claims, is not percussive.

Moreover, in a claim drawn to a process, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Therefore, Applicant's arguments that the instant methodology is directed for improving wounds in diabetic animals are not persuasive, because there is no difference in the method steps of the instant claims and those taught by the combined teachings of the cited references.

Finally, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, all cited prior art are in the same field of endeavor. The nature and process of studying the efficacy of compounds for wound healing is well established. In fact, Applicant disregards the common knowledge available by Jones that ARIs normalize accumulation of sorbital in sciatic nerve, thus, reversing the diabetic associated symptoms. Subsequently, it follows from such suggestion that ARIs can be used as a control for comparative studies. Thus, it would have been obvious to one of

ordinary skill in the art at the time of invention to employ it for diabetic associated wounds as well for the reasons of record. finally.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200